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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,675

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Jeffrey Burbank

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MILES & STOCKBRIDGE PC
1751 PINNACLE DRIVE
SUITE 500
MCLEAN, VA 22102-3833

EXAMINER

MENON, KRISHNAN S

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

08/06/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/585,675	Applicant(s) BURBANK, JEFFREY	
	Examiner Krishnan S. Menon	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-46 and 52-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-46 and 52-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of claims 31-46 and 52-54 in the reply filed on 7/23/10 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for discontinuing pumping when the unique identifier is read by the controller, does not reasonably provide enablement for stopping pumping when the unique identification is read by another controller. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Claims 31 (and 33) recites in the last paragraph that the pumping is discontinued when the same unique identifier is read by another similar controller. This part is not enabling and would require undue experimentation for one of skill in the art to practice.

Claims recite detecting imminent failure of the filter, which is non-enabling. Imminent failure is some thing that would happen in future, and it is unclear how applicant would detect this for any and all kinds of filters the claims encompass. Claims are broad and include all kinds of filters. Applicant's disclosure provides a dual ion

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exchange filter in which when the first larger filter fails, the predetermined quantity of fluid is estimated based on the remaining useable life of the second smaller filter.

However, claims recite only one filter and are open to any filter. Thus the claims are non-enabling for the breadth they encompass.

For examination, it is assumed an actual failure in the recitation "imminent failure"

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following part of claim 31 is unclear:

said controller also being configured to control the pump to continue pumping until a predetermined quantity of fluid has been pumped if, during a pumping operation, said fluid quality sensor gives a second indication indicating that said filter module will fail imminently, but thereafter to control the pump to not pump fluid if a same unique identifier is read as when said second indication was received by it or by another similar controller.

This part reads as if pumping is continued to a predetermined quantity if the filter has failed, but pumping stopped thereafter if the unique identifier is read again a second time. It is unclear when the pumping would be stopped: when the predetermined quantity is pumped, when the filter fails, or when the unique identifier is read again? Also unclear is what the "another controller" would receive: the unique identification or

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the second indication or both? How are the two controllers linked? Other claims have the same or similar problems. Is “another controller” part of the structure claimed?

For examination, this “another similar controller” is ignored. It is in the alternate, any way.

Claims Analysis

Broadest is claim 34, which recites a filter and a controller, wherein the controller is configured to read a unique identifier in the filter and quality of water downstream of the filter using a sensor, and then continue operation based on the water quality reading, and in case of any indication of failure, to discontinue production after a predetermined quantity of water is produced.

Other additional elements in the claims include (1) first and second filters or first and second filter stages, with sensor between them, so that when the first filter fails, production continues to a predetermined volume base on the life of the second filter; (2) filters are deionization filters, and sensor is a conductivity sensor (3) the controller configured to add a token to the filter indicating that it is used; (4) operation of the filter is using a pump; (5) intended use is for extracorporeal blood treatment; (6) first filter/filter stage include separate anion and cation exchange beds and second filter/stage is mixed bed.

The basic inventive idea appears to be providing two ion-selective filter stages with a sensor in between, so that when the first stage fails, the second stage provides

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the safety of providing enough water for the extracorporeal blood treatment device to complete the treatment process.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-46 and 52-54 are rejected under 35 USC 103(a) as being unpatentable over the combination of Astle et al (US 2003/0168389), Selby (US 4,246,101) and Carson et al (US 2006/0021944)

Astle teaches a controller and a filter module, sensors to determine the filter quality or useful life, and the controller being configured to identify a unique identifier on the filter using bar code, electronic or magnetic signature, etc. The controller is also capable of communication with the data carrier on the filter for exchange of information, and capable of identifying the compatibility and the status of the filter. See abstract, figures and paragraphs 0041 - 0050.

Paragraph 0047 – 0049 teaches providing memory chips on the filter which can communicate with the control system to exchange information on useable life of the filter and predict end of life, etc. Astle system is capable of the operation described in the claims, such as reading a change in the status of the filter with a same unique

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identifier in a second reading triggering an operation to have a specified volume of liquid being produced before shut down to replace or regenerate the filter. This element of the claims is purely operational and would not add to patentability when the prior art device is so capable.

Astle does not explicitly teach a water quality sensor such as a conductivity or resistivity sensor, even if it teaches regenerative type filters [0038].

Selby teaches a water treatment system in which, among others, an ultrafiltration unit followed by a nephelometer to measure the turbidity of output water, adsorbers followed by TOC monitor, and ion exchange beds followed by conductivity meter (see figures) to measure the TDS of water. Selby also teaches microprocessors and automated switching of the ion exchange beds for regeneration or shut down based on water quality output. Column 3, lines 50-57, column 4, lines 44-68; column 5, lines 38-68. The reference teaches individual and mixed beds – column 6, lines 14-20, column 8, lines 15-34; column 7, line 60 – column 8, line 11.

Selby teaches automatic recycle of water that does not meet quality and regeneration of the resin beds, adsorber beds, and the filters using appropriate water quality sensors/detectors. The monitoring and controls are by microprocessors. However, Selby does not appear to teach programming the controller based on the remaining life of the various filter units.

Selby also teaches automated regeneration including the location of the regenerate in the beds with monitors (see column 4, lines 10-17). Multiple beds are so

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sized as to require regeneration at the same time, which implies that they could also be individually monitored and regenerated – column 4, lines 18-30.

It would, therefore, be obvious to combine the teachings of Selby and Astle to complement each-other to have the capability of predicting the remaining life of the various filters, including the ion-selective filters. Such a combination would be capable of predicting the end of life of the ion selective filters to provide a predetermined quantity of water before the system shut-down. Particularly, the teaching of in combination with Selby makes it possible to determine the remaining life of the filter system so that the quantity of water it can produce at any time is predictable.

However, Astle and Selby do not explicitly teach providing a redundant second stage ion selective filter that will take up the load for the predetermined volume of treated water after the first stage has reached the end of its life as is required in some of the claims.

Carston teaches in Fig 4 and paragraphs 0051 and 0052 redundant ion exchange beds wherein the upstream stage is sufficient to provide the water quality, but a second downstream redundant stage is provided to treat the water when the detector between them shows that the upstream stage is exhausted.

Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to have the teaching of Carson in the teaching of Astle and/or Selby to provide the redundant second stage filter to continue to produce the treated water of the required quality even if the first stage filter failed during operation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1797